DEPARTMENT OF HEALTH & HUMAN SERVICES

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Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive S.E.
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

October 7, 1999

VIA FEDERAL EXPRESS

In reply refer to Warning Letter SEA 00-03

Richard M. Kaer, Owner
Breakwater Seafoods
319 Ocean View Drive
Wrangell, Alaska 99929

WARNING LETTER

Dear Mr. Kaer:

On August 3, 1999, the Food and Drug Administration (FDA) conducted an inspection of your facility located at 319 Ocean View Drive, Wrangell, Alaska. At the conclusion of the inspection, [redacted] was presented with a Form FDA 483 listing serious deviations from Title 21 of the Code of Federal Regulations (21 CFR) Part 123 - Fish and Fishery Products (HACCP Regulation). A copy of that Form FDA 483 is enclosed for your review. By virtue of these deficiencies, the live crab processed by your firm are adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) and 21 CFR Part 123.

Your firm did not have a written HACCP plan for live crab. Our investigators identified natural toxins in live crab as a potential hazard.

21 CFR Part 123.6(a) requires every seafood processor to conduct a hazard analysis to determine whether there are food safety hazards that are reasonably likely to occur for each kind of seafood product it manufactures and to identify preventive measures to control those hazards. 21 CFR Part 123.6(b) requires firms to have and implement a HACCP plan when one or more food safety hazards, that are reasonably likely to occur, are identified. In accordance with 21 CFR Part 123.6(c), the contents of your HACCP plan should include specific hazards and critical control points for each identified hazard. For each critical control point, adequate critical limits, monitoring procedures, record keeping procedures and verification procedures must be established.

During the previous inspection, on August 6, 1998, and in a letter from the FDA, dated March 17, 1999, you were notified of the same deficiencies described above in paragraph two of this

letter. During the inspection, and in the letter, the FDA explained that you would need to take steps to correct those deficiencies. The FDA is concerned that in fourteen months time, your firm has not taken action to correct these deficiencies.

The above HACCP violations are not meant to be an all-inclusive list of deficiencies in your plant. Other violations can subject the food to legal action. It is your responsibility to assure that all of your products are in compliance with applicable statutes enforced by the FDA. You should take prompt action to correct all of the violations noted in this letter. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing, within 15 working days of the receipt of this letter, of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 working days, state the reason for the delay, and the time within which the corrections will be completed. Pertinent sections of the Act and the Regulations are enclosed for your review. Your reply relating to these concerns should be addressed to the Food and Drug Administration, Attention: Diane J. Englund, Acting Compliance Officer, 22201 23Rd SE, Bothell, Washington 98021-4421.

Sincerely,

Austin R. Long, Ph.D.
Acting District Director

Enclosures:
Form FDA 483
21 CFR PART 123
Section 402 of the Federal Food, Drug, and Cosmetic Act

cc: ADEC with disclosure statement